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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,595	02/18/2004	Naim Istephanous	4002-3450/PC777.00	2667

52196 7590 03/12/2007  
KRIEG DEVAULT LLP  
ONE INDIANA SQUARE, SUITE 2800  
INDIANAPOLIS, IN 46204-2709

EXAMINER
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SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/781,595

Applicant(s)

ISTEPHANOUS ET AL.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) 19,34-43,46-48 and 65-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18,21-28,44-58 and 64 is/are rejected.
- 7) ☒ Claim(s) 20,29-33 and 59-63 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/24/05; 8/2/04; 11/1/04</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, disc prosthesis of figure 1, titanium metal matrix, titanium carbide reinforcing component, homogeneous dispersion in the reply filed on 12/26/06 is acknowledged. The traversal is on the ground(s) that all figures are disc prosthesis. This is not found persuasive; the Examiner's election of species is based on applicant's identification of the patentably distinct devices in the specification, page 4, "Brief Description of the Figures". The election notes four patentably distinct devices identified in figure 1, figure 3, figure 5, figure 8. It is noted that the term "disc" is more specific than "spinal".

The requirement is still deemed proper and is therefore made FINAL. Claims 19, 34-43, 46-48, 65-96 have withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species.

### ***Information Disclosure Statement***

The information disclosure statement filed 1/24/05 and 11/01/04 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed 8/2/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each

non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26 and 27, what is the scope of "exhibits"? Does the plate have two different porosities?

***Allowable Subject Matter***

Claims 20, 29-33, 59-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 26 and 27 are would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 103***

Claims 1-8, 14, 16-18, 21-25, 44-52, 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over SDGI (WO 00/23015) in view of Landingham (2003/004914).

SDGI teaches:

1. A spinal implant assembly for insertion between adjacent first and second vertebrae, said implant comprising:
  - a first plate 22 including a first surface configured to engage the first vertebra and an opposite second surface, and
  - a second plate 24 including a third surface configured to engage the second vertebra and a opposite fourth surface having a bearing portion configured engage the second surface of the first plate; SDGI teaches the implant can be made of titanium (pg 15, lines 30-36).

However, SDGI is silent regarding, wherein said first and second plates comprise a metal matrix composite including a metallic matrix and a reinforcing component dispersed within the metallic matrix.

Landingham teaches this material configuration known as a cermet having a metal matrix such as titanium and a reinforcing component such as aluminum oxide; and the material can be used as implant joints. It would have been obvious to one having ordinary skill in the art to have utilized the titanium cermet material taught by Landingham in the spinal implant of SDGI because *"[c]urrently, both alumina and titanium alloys are acceptable and FDA approved implant materials. These materials*

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*alone or in combinations, fabricated by methods known in the art do not possess the desired properties required for bond or joints replacement. However, because of the new processing, the cermets of the invention made of these two materials have similar properties as bones or joints to be replaced and have, in addition to other already listed properties, also an elasticity modulus and surface finish which prevents wear in the joint area and allows an attachment of the ligaments or other tissues."*

Regarding at least claim 6, see paragraph 0021.

Regarding the claimed hardness, same materials inherently have the same properties.

Regarding at least claim 24, SDGI states alternative attachment structures may be used, see page 15, lines 24 et seq. It would have been obvious to one having ordinary skill in the art to have used any of the know claimed structures including teeth of the device of SDGI and Landingham to better secure the implant to the host bone.

Claims 9-13, 28, 44, 52, 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over SDGI (WO 00/23015) and Landingham (2003/004914) and further in view of Despres, III, et al (6,261,322).

SDGI and Landingham teach the implant as described above, however, fail to teach a first surface having a porosity. Despres teaches a coating a porous in-growth layer on implants such as spinal implants (3:3). It would have been obvious to one having ordinary skill in the art to have used the coating of Despres of the implant of

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SDGI and Landingham to allow for tissue in-growth and better anchoring of said implant. The coating can be interpreted as being a portion of the metallic matrix material.

Regarding the porosity of greater than about 5 percent, this range would be obvious to one having ordinary skill in the art to allow for tissue in-growth.

Regarding a therapeutic agent, see 8:8 et seq.

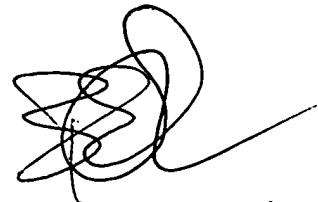
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

**BRUCE SNOW**  
**PRIMARY EXAMINER**